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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,608	06/26/2003	Philip D. Hayes	GP70745B-C5D1	8994

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EXAMINER	
GEBREYESUS, KAGNEW H	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)	
	10/606,608	HAYES ET AL.	
	Examiner	Art Unit	
	Kagnew H. Gebreyesus	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

Priority is recognized for this application as it is a divisional of application Serial No. 10/324,981, filed 20 December 2002, which is a continuation of application Serial No. 10/1 17, 166, filed 05 April 2002, which is a continuation of application Serial No. 09/963,266, filed 26 September 2001, which claims the benefit of utility application Serial No. 09/489,650, fled 24 January 2000, which is now abandoned.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 is rejected for the recitation of "over the entire length thereof". It is not clear whether applicants refer to the entire length of SEQ ID NO: 1 or the complementary sequence claimed in claim 2(j).

Claim 2 and dependent claims 5-9 are indefinite in the recitation of "stringent conditions" as the specification does not define what conditions constitute "stringent". While page 6 of the specification describes some conditions which are intended to be stringent, there is nothing to suggest that other conditions would not also be included within the scope of this term and in the art what is considered stringent varies widely depending on the individual situation as

well as the person making the determination. As such it is unclear how homologous to the sequence of a gene encoding SEQ ID NO: 1, a sequence must be to be included within the scope of these claims.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide sequence (DNA or RNA) of SEQ ID NO: 1, a sequence that is at least 95% identical to SEQ ID NO: 1 over the entire length and encoding a polypeptide with methionyl tRNA synthetase activity, vectors and host cells comprising the same, a process of expressing and producing the encoded polypeptides, the polypeptide of SEQ ID NO: 2, a polypeptide 95% identical to the entire sequence of SEQ ID NO: 2 with methionyl synthetase activity does not reasonably provide enablement for any variant of a polynucleotide sequence (DNA or RNA)/polypeptide of SEQ ID NO: 1/SEQ ID NO: 2 or any polynucleotide (DNA or RNA)/polypeptide that is at least 95% or more identical to any segment of SEQ ID NO: 1 or SEQ ID NO: 2. In addition claim 2(i) encompasses any polynucleotide with at least 100 nucleotides or more with the only limitation that said sequence hybridizes with a 15 nucleotide sequence fragment from SEQ ID NO: 1. Furthermore while the specification is enabling for an antibody immunospecific for the polypeptide of SEQ ID NO: 2 does not reasonably provide

enablement for all antibodies immunospecific for any variant of the polypeptide of SEQ ID NO: 2 or any polypeptide that is at least 95% or more identical to any fragment of SEQ ID NO: 2.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 2 and dependent claims 3, 5-9 are so broad as to encompass any DNA having a polynucleotide sequence that in it's sequence comprises a sequence that shows 95% or more identity to SEQ ID NO: 1 with or without methionyl synthetase activity or any variant of the polynucleotide (DNA or RNA) which is at least 95% or more identical to any fragment of SEQ ID NO: 1 with or without methionyl synthetase activity (i.e. any fragment of SEQ ID NO: 1 and all variants), vectors and host cells comprising said DNA sequences. These claims are not limited to the sequences of SEQ ID NO: 1 or a polynucleotide sequence that are 95% identical to the entire length of SEQ ID NO: 1 with methionyl synthetase activity but also encompass fragments of SEQ ID NO: 1 and longer sequences where the only limitation is that they comprise (include) SEQ ID NO: 1 with or without methionyl synthetase activity.

Likewise claims 1 not only encompasses the polypeptide sequence of SEQ ID NO: 2 and sequences that show 95% identity to SEQ ID NO: 2 on the entire length with methionyl synthetase activity but also sequences that are larger and smaller fragments of SEQ ID NO: 2 without methionyl synthetase activity. In addition antibodies immunospecific to all of said polypeptides variants is beyond the scope enabled by the specification.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of nucleic acid/polypeptide sequences,

vectors and host cells comprising said nucleic acid sequences in addition to antibodies broadly encompassed by the claims. In addition any polynucleotide with at least 100 nucleotides or more with the only limitation that said sequence hybridizes with a 15 nucleotide sequence fragment from SEQ ID NO: 1 can encompass an enormous number of polynucleotide sequences unrelated the polynucleotide sequence(s) enabled by the specification.

While recombinant and mutagenesis techniques modifying limited number of residues at specific positions are known, it is not routine in the art to screen for multiple substitutions as encompassed by the claims. Since the nucleic acid sequence of a gene encoding the corresponding protein determines its structural and functional properties, predictability of which changes can be tolerated in the nucleic acid sequence and obtain the desired activity of the encoded protein requires a knowledge of and guidance with regard to which nucleotide(s) in the DNA sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the nucleic acid structure relates to the function of the encoded protein. However, in this case the disclosure is limited to polynucleotide sequences, vectors and host cells comprising the same and encoded polypeptide sequences and antibodies wherein the polynucleotide sequences are 95% or more identical to SEQ ID NO: 1 and the polypeptide sequences are 95% identical to SEQ ID NO: 2 in their entire length.

The scope of the instant claims encompasses multiple modifications (deletions, additions etc), however no disclosure was provided with regards to the positions within the DNA sequence where nucleic acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility of the polynucleotides or the encoded polypeptides. Such

modifications are limited in any sequence and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given polynucleotide/polypeptide to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass any polynucleotide sequence (DNA or RNA) comprising a sequence that is 95% identical to SEQ ID NO: 1 or any polynucleotide (DNA or RNA) that is at least 95% or more identical to any segment of SEQ ID NO: 1 in addition to any polynucleotide with at least 100 nucleotides or more with the only limitation that said sequence hybridizes with a 15 nucleotide sequence fragment from SEQ ID NO: 1. Likewise the specification does not support the broad scope of the claims which encompass any polypeptide comprising in said polypeptide sequence, a polypeptide sequence that is 95% identical to SEQ ID NO: 2 or polypeptide that is at least 95% or more identical to any segment of SEQ ID NO: 2. Furthermore the specification does not support the broad scope of the claims which encompass all antibodies immunospecific for any polypeptide comprising in it's sequence the polypeptide of SEQ ID NO: 2 or any polypeptide that is at least 95% or more identical to any fragment of SEQ ID NO: 2 because the specification does **not** establish: (A) regions of the polynucleotide structure which may be modified without effecting activity or immunospecificity of the encoded protein; (B) the general tolerance of polynucleotide sequence to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any nucleotide residues in SEQ ID NO: 1 with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any polynucleotide sequence (DNA or RNA)/polypeptide comprising in said polynucleotide/polypeptide sequence a polynucleotide/ polypeptide sequence that is 95% identical to SEQ ID NO: 1/SEQ ID NO: 2 or any polynucleotide (DNA or RNA)/polypeptide that is at least 95% or more identical to any segment of SEQ ID NO: 1 or SEQ ID NO: 2. In addition claim 2(i) encompasses any polynucleotide with at least 100 nucleotides or more with the only limitation that said sequence hybridizes with a 15 nucleotide sequence fragment from SEQ ID NO: 1. The scope of this claim is enormous.

Furthermore the specification does not reasonably provide enablement for all antibodies immunospecific for any polypeptide comprising in it's sequence the polypeptide of SEQ ID NO: 2 or any polypeptide that is at least 95% or more identical to any fragment of SEQ ID NO: 2.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polynucleotide/polypeptide sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. These claims are directed to a genus of DNA molecules with either SEQ ID NO: 1 or any DNA which is 95% identical to SEQ ID NO:1 and variants thereof or DNA having the limitations of encoding a protein having the SEQ ID NO:2 or encodes a protein that is 95% identical to SEQ ID NO:2.

The specification does not contain any disclosure of the function of all DNA sequence variants of SEQ ID NO:1 or all variants of the polypeptide of SEQ ID NO: 2. The genus of polynucleotides/polypeptides that comprise these above molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated polynucleotide/polypeptides are encompassed within the scope of these claims, including partial polynucleotide/polypeptides sequences. The specification discloses only a single species of the claimed genus SEQ ID NO: 1 or 2 which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1- 9 are rejected under 35 U.S.C. 102(a) as being anticipated by Ruben et al. (US 20030109690 A1). Ruben et al. disclose a sequence showing 95.4% best local similarity to the region between 695-1061 of SEQ ID NO: 1 of the instant application. Given that this sequence is within the limitation of claim 2 as explained in the above rejection under 35 U.S.C. 112, first paragraph it constitutes prior art under 35 U.S.C. 102(a). In addition Ruben et al disclose vectors, host cells comprising the polynucleotide sequence and antibodies specific to the polypeptides and method of producing the polypeptides encoded by the polynucleotide they disclose thus anticipating claims 1 and claims 3-9 (see claims in reference).

4. Claims 1, 2, 5-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Martinis et al. Martinis et al (US PAT 5,798,240) disclose the polynucleotide sequence of a micobacterial tRNA synthetase gene, vectors and host cells carrying said sequence, and polypeptides obtained by expressing the same. The polynucleotide sequence shows 38.3% similarity to the polypeptide of SEQ ID NO: 2. and a polynucleotide sequence showing 51.3 % similarity to the poynucleotide sequence of SEQ ID NO: 1. These sequences are within the limitation of claims 1 (polypeptide) and 2 (polynucleotides) as they would be encompassed within the scope of variants of SEQ ID NOs: 1 and 2 therefore anticipate the sequences claimed in the instant application. In addition, vectors comprising the polynucleotide sequence and method of expression the encoded polypeptides in a host cell is also disclosed by Martinis et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagnew H. Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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